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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,919	09/01/2006	Jude A. Oben	OB080-000OB	1397

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STITES & HARBISON, PLLC
400 W MARKET ST
SUITE 1800
LOUISVILLE, KY 40202-3352

EXAMINER	
MARSCHEL, ARDIN H	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,919	OBEN ET AL.	
	Examiner	Art Unit	
	ARDIN MARSCHEL	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-18 is/are rejected.

7)☒ Claim(s) 4-8, 10, and 12-16 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 1/10/08.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants are hereby informed that, in view of the claim amending, filed 9/28/05, the previous office action, mailed 7/11/07, is hereby vacated and replaced as summarized below. The citations on the form 892, mailed 7/11/07, however, are understood to remain of record in the instant application history.

IMPROPER "USE" CLAIM WORDING

Claims 11-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-18 provides for the use of an agent, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 11-18 are also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

Claims 1-8, 10-16, and 18 are rejected under 35 U.S.C. § 112, first paragraph, as

containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses two chemicals, prazosin and 6-hydroxydopamine, which meet the written description and enablement provisions of 35 USC 112, first paragraph regarding chemicals with structures that are agents for mobilization of stem cells as described in the substitute specification on page 1, last 17 lines. It is noted that propanalol per se is not described as being a stem cell mobilization agent. However, claims 1-8, 10-16, and 18 are directed to encompass such agents, which only correspond in some undefined way as such agents as unlimited as to specific agents corresponding to the phrase "an agent for mobilizing stem cells" set forth in instant claim 1. None of such unnamed these agents meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical

structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

REJECTION(S) UNDER 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 6, 9, 11, 13, 14, and 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by McLean (P/N 6,174,917).

McLean teaches a method for treatment of liver disease including cirrhosis, toxic and medicamentary liver damage, and other disorders with vasodilators given in column 3, liens 30-35, including in a short list, prazosin as instantly cited in instant claims 9 and 17 as an SNS regulator. This is therefore disclosure of reasonably a SNS regulator embodiment of instant claims 2-3 and 11 also via dependence which thus anticipates the above listed instant claims. Dubuisson et al. (P/N 6,649,615) is cited herein to indicate evidence that prazosin is an adreno receptor antagonist as disclosed in column 1, lines 45-48, thus supporting rejection of instant claims citing usage of such an antagonist. Further Dubuisson et al. at column 4, lines 1-12, discloses prazosin as an alpha-adrenoreceptor antagonist.

Claims 1-3, 5, 6, 9, 11, 13, 14, and 17 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Dubuisson et al. (P/N 6,649,615).

Dubuisson et al. (P/N 6,649,615) discloses that prazosin is an adreno receptor antagonist as disclosed in column 1, lines 45-48, thus supporting rejection of instant claims citing usage of such an antagonist. Further Dubuisson et al. at column 4, lines 1-12, discloses prazosin as an alpha-adrenoreceptor antagonist. In the abstract of Dubuisson et al. the invention is directed to hepatic fibrogenesis treatment. Cirrhosis is

cited as an endpoint of such fibrosis in column 2, lines 60-63, and thus the reference teaches treatment inclusive of liver disorder as instantly claimed. Column 2, lines 45-59, cite other liver disorders including damaged liver as instantly claimed as being treated via the reference's pharmaceuticals. Both 6-hydroxydopamine (OHDA) and prazosin are disclosed in the reference in column 2, lines 24-63, as utilized for treating liver disorders or damage as instantly claimed thus anticipating the above listed instant claims.

OBJECTIONS

The disclosure is objected to because of the following informalities:

The abstract contains the misspelled word "Prazocin".

In claims 4-8 and 12-16, the limitations "adrenosceptor" and "adrenoceptor" are a misspelling of "adrenoreceptor".

In claim 8, line 2, the type of adrenoreceptor being beta-20 appears to be a misprint.

In claim 10, line 1, "regulagtor" is misspelled.

In claim 16 line 1, the phrase "claim 1r4" contains a confusing claim number.

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., Supervisory Patent Examiner, AU 1614, whose telephone number is (571)272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 10, 2008

Ardin H. Marschel 1/10/08

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER